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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,744	03/22/2002	Willy Deleersnijder	01975.0034	5092

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,744	Applicant(s) DELEERSNIJDER ET AL.	
	Examiner John D. Ulm	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-69 is/are pending in the application.
- 4a) Of the above claim(s) 22-25,27,30,32,35,37,47,49,51,57-59 and 61-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-21,26,28,29,31,33,34,36,38-46,48,50,52-56,60,68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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1) Claims 1, 2 and 5 to 69 are pending in the instant application. Claims 1, 5 to 8, 10, 14 to 20, 26, 28, 29, 31, 33 to 36, 38 to 40, 42, 52, 53 and 60 have been amended as requested by Applicant in the correspondence filed 03 September of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 22 to 25, 27, 30, 32, 35, 37, 47, 49, 51, 57 to 59 and 61 to 67 stand withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper filed 08 January of 2004.

5) Applicant is advised that a claim drawn to "an isolated nucleic acid encoding a neuromedin receptor protein of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8" would be allowable. Applicant is further advised that claim 1 would be allowable if the limitation "wherein the polypeptide is an IGS4 polypeptide" was deleted therefrom and/or replaced by the limitation "wherein the polypeptide is a neuromedin receptor protein". Claim 17 would also be allowable if the limitation "IGS4" were deleted therefrom and/or replaced with the limitation "neuromedin receptor".

6) Claims 21, 26, 31 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A

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properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 21 is improper because it refers to an amino acid sequence of claim 17 rather the isolated polypeptide to which claim 17 is directed. The method of each of claims 26 and 31 does not actually employ an "isolated" polypeptide of claim 17 or an IGS4 polypeptide having any recited structural limitations. Claim 38 is improper because it can be infringed by a process that does not employ a membrane preparation of claim 14.

7) Claims 6 to 8, 42 and 43 are rejected under 35 U.S.C. § 101 because they are drawn to non-statutory subject matter for those reasons of record as applied to claims 6, 8, 17, 18, 26, 31, 39, 40, 42, 43, 52, 53, 68 and 69 in section 7 of the previous office action. Claim 6, for example, is still drawn to a nucleotide "sequence". A "sequence" is a property of a compound and properties, such as shapes, sizes, colors and sequences are not subject to patentability.

8) Claims 9, 11 to 13, 15, 16, 18, 31, 36, 60, 68 and 69 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims essentially for those reasons of record as applied to claims 6 to 16, 18 to 20, 28, 29, 31, 33, 34, 36, 42 to 45, 48, 50, 54 to 56, 60, 68 and 69 in section 8 of the previous office action. As stated therein, the only "IGS4 neuromedin receptor protein"

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that is described in the instant specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is a protein comprising any one of the four amino acid sequences presented in SEQ ID NO:2, 4, 6 and 8 of the instant application. Further, in so far as these claims encompass a neuromedin receptor protein lacking one of the four disclosed amino acid sequences or a protein encoded thereby, the instant specification provides neither a written description of such a nucleic acid or protein, or the guidance needed to produce it.

Applicant has traversed this rejection on the premise that "as amended, the claims recite the sequences of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8, and are limited to these sequences". This position is not supported by the actual claim limitations, which still permit modifications to as much as 20% of the recited sequences. In fact, claim 31 places no structural limitations of the "IGS4 polypeptide" employed therein. Therefore, this rejection is maintained against the instant claims for those reasons of record.

9) Claims 1, 2, 5 to 21, 26, 28, 29, 31, 33, 34, 36, 38 to 46, 48, 50, 52 to 56, 60, 68 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9.1) Claims 1, 2, 5 to 21, 26, 28, 29, 31, 33, 34, 36, 38 to 46, 48, 50, 52 to 56, 60, 68 and 69 are vague and indefinite in so far as they employ the term "IGS4" as a limitation for those reasons of record in section 10.1 of the previous office action.

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Applicant has traversed this rejection on the premise that this term "is not recited in the claims as a limitation, but as a further characterization of the sequence recited" therein.

Application is advised that a term recited in a claim is a limitation on the claimed subject matter. The rejection is maintained because the metes and bounds of the limitation "IGS4" are not determinable in view of the specification and art of record.

9.2) Claims 19 and 20 are confusing because the relationship between the limitation "SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8" and "an amino acid sequence of a neuromedin receptor protein" is unclear. Further, the limitation wherein "said protein exhibiting high affinity" is grammatically incorrect and should be "wherein said protein exhibits high affinity".

9.3) Claims 8, 19 to 21, 28, 33, 34, 43, 45, 46, 50 and 60 are vague and indefinite because the "high affinity" is conditional and no single set of defining conditions can be found in the claims or the specification. Applicant has traversed this rejection on the premise that this limitation "is clearly defined in the specification", "specifically, on page 14, lines 16-19". It is noted that the text relied upon by Applicant does not provide a "single set of defining conditions" to which a practitioner could refer in trying to determine if a particular compound infringes the claim. To the contrary, that text recites a broad value followed by a series of progressively narrower values. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex*

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parte Wu, 10 USPQ2d 2031; 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

9.4) Claim 42 is vague and indefinite because there is no antecedent basis for "the isolated polynucleotide of claim 6", which is drawn to "an isolated nucleotide sequence".

10) Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting an essential element, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element in each of these claims is an expression system encoding SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, or SEQ ID NO: 8.

11) Applicant's arguments filed 03 September of 2004 have been fully considered but they are not persuasive.

12) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

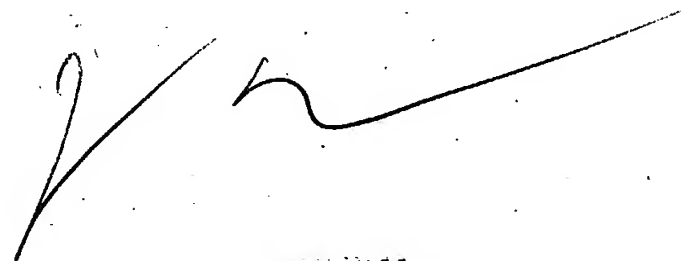
13) This application contains claims 22 to 25, 27, 30, 32, 35, 37, 47, 49, 51, 57 to 59 and 61 to 67, which are drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brunback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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